The arrival of a true point-of-care molecular assay—ready for global implementation?

The arrival of the next generation of advanced diagnostic point-of-care tests was announced on July 28, 2015, when Cepheid and their non-profit partner, FIND, unveiled a new device called GeneXpert Omni.[1] Although this device might seem to be yet another rapid nucleic acid amplification test, it is small (23 cm tall), lightweight (1 kg), easy to use, powered by a rechargeable battery, and has wireless connectivity, making it the first true point-of-care molecular assay. This portable device will allow health-care workers to do sophisticated molecular testing in the most remote areas of the world. Since it operates all the same PCR-based cartridge tests as Cepheid's existing GeneXpert, it is already capable of performing multiple diagnostic tests, including tests for tuberculosis, drug-resistant tuberculosis, HIV, and Ebola virus.

GeneXpert Omni builds on the global successes of first-generation diagnostic point-of-care tests and Cepheid's laboratory-based GeneXpert system.[2] These first-generation tests are straightforward assays to indicate the presence (or amount) of a molecule or an antigen on a strip of paper,[3] and they have substantially improved the management and diagnosis of important conditions and diseases. For example, millions of patients with diabetes worldwide optimise their blood sugar level by inserting a blood-saturated strip of paper into a small, battery-powered glucometer;[4] women collectively use roughly 300 000 urine tests per day in the comfort of their home to know their pregnancy status;[5] and rapid HIV tests have helped 600 million adults to know their HIV serostatus in 122 low-income and middle-income countries in 2010–14.[6]

Cepheid's GeneXpert system achieved recognition as a rapid molecular test to identify active tuberculosis and rifampicin resistance, a marker for multidrug-resistant tuberculosis.[7] So far, more than 13 million Xpert *Mycobacterium tuberculosis*/rifampicin (MTB/RIF) tests have been done worldwide.[1] However, the primary criticism has been that implementation of rapid GeneXpert testing in reference laboratories has had little effect on reaching the 3 million individuals with *M tuberculosis* infection who remain undiagnosed each year.[8] What had been lacking, until now, was an accurate, portable device to allow health-care workers to actively identify infected patients in the community, thereby breaking the cycle of tuberculosis transmission.

GeneXpert was designed to identify several infectious organisms and genetic biomarkers, and the machines are operating in laboratories around the world. The system can already identify eight hospital-associated infections, 12 additional infectious diseases, and genetic markers for cancer (*BCR–ABL*) and thrombosis risk (Factors II and V), with several more tests in development.[9] By using the same platform, the portable Omni gives health-care workers the ability to do all the same cartridge-based tests in the community.

Although the ability to do advanced nucleic acid testing in remote, resource-limited settings could change the approach to global health delivery, discussion of the potential challenges is needed before widespread implementation. First, an agreement must be reached about regulatory assurances and quality control measures to ensure oversight for maintenance of the integrity and accuracy of diagnostic testing. Although GeneXpert Omni has wireless connectivity for remote result monitoring, who will be responsible for such a task is unclear. Second, in view of the existing global shortage of laboratory expertise,[10] there is little understanding of whether community-based testing might place an additional strain on laboratory systems by requiring

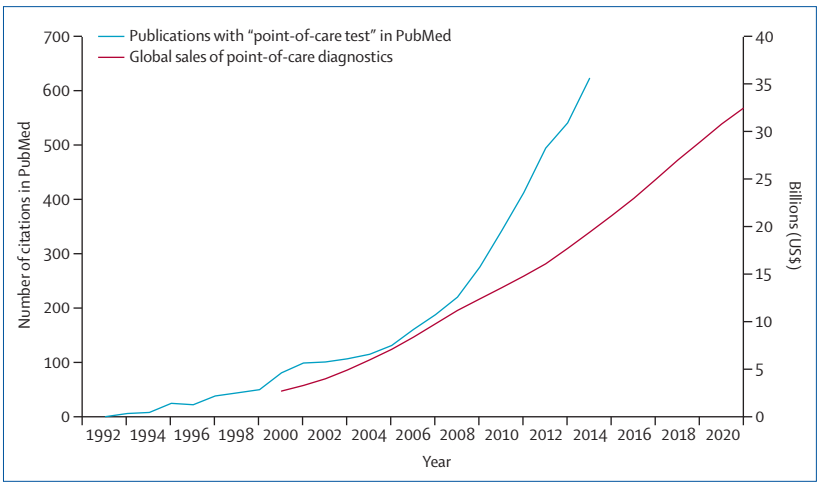

Figure: **Estimated annual research and global market for point-of-care diagnostics**
The annual number of citations was determined by a customised search in the PubMed database for the term "point-of-care test". The estimated global market data were provided by Visiongain.[11]

more staff resources and logistical support, or whether effective point-of-care testing could help to offload some of the burden on laboratory workers. Third, no clear guidance exists to help stakeholders to decide on the adoption of novel point-of-care tests. Should each new device or test be required to show greater accessibility to testing or better patient outcomes than existing ones? If so, then each device or test might need to be assessed in clinical implementation trials and analysed for its cost-effectiveness, which will be time consuming and costly.

These are just some of the topics that will need an open discussion between public health officials, hospital and clinic administrators, laboratory managers, clinicians, and outreach workers. GeneXpert Omni has set a new bar for true point-of-care molecular assays and opened the door for a range of applications, from improved contact tracing for infectious diseases to community-based screening for certain cancers. The global research and market for diagnostic point-of-care tests will continue to grow rapidly over the coming years (figure).[11] However, for these tests to have a positive effect, dialogue among the various stakeholders should begin now.

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We declare no competing interests.

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